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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/114,285 07/13/98 TSUCHIYA

M 53466/234 <sup>VB</sup>

HM22/0703

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EXAMINER

BANSAL, G

ART UNIT

PAPER NUMBER

1642

10

DATE MAILED:

~~07/03/00~~

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/114,285

Applicant(s)

Tsuchiya et al

Examiner

Geetha Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/13/00 and 3/13/00 and 11/18/99 <sup>IDS.</sup>
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 69-76 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 69-76 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1 sheet <sup>IDS 11/17/99</sup>
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

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### **DETAILED ACTION**

1. Applicant's amendment filed April 13, 2000 (Paper No: 9/A) is acknowledged. Accordingly, the application has been amended to insert SEQ ID Nos. where required. Claims 67-76 are being examined.

### ***Response to Arguments***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.


3. The claims are drawn to a chimeric antibody to the human IL-6R comprised of human constant regions and murine variable regions. The claimed antibody comprises the variable regions of the murine anti-IL-6R antibody termed PM-1, the amino acid sequence of which is recited in the claims.

4. Rejection of claims 69-76 under 35 U.S.C. 103 (a) is maintained. Applicant's arguments have been considered but are not persuasive for the following reasons. Applicant argues that the reference of Hirata or Kishimoto et al do not teach the unexpected and superior properties of the claimed chimeric antibodies with respect to inhibition in the growth of multiple myeloma cells. Further, Applicant states that Hirata et al "only teach human IL-6R, and hybridomas producing these antibodies". It is submitted that Hirata et al teach antibodies and hybridomas producing antibodies against the human IL-6R and also teach the antibody PM-1 which is the murine antibody that is the source of the variable region that is used to make the claimed chimeric antibody. In view of that the biological and biochemical properties of the said antibody is an intrinsic property of the antibody and its binding activities are dictated by the variable regions (as for the PM-1 antibody for e.g.). Applicants arguments, drawn to the unexpected and superior properties, are not commensurate in scope with the claims which are drawn to the chimeric

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antibody and nucleic acid encoding the chimeric antibody ((see page "Remarks" 3rd paragraph)-Applicant is requested to number the response pages for ease of reference, in forthcoming responses). The evidences in the form of references submitted in favour of the unexpected properties of the claimed antibodies have been reviewed. It is apparent that the references do not suggest any unexpected or superior properties as for e.g. Sato et al acknowledges that the original murine antibody bound to the human IL-6R and inhibited multiple myeloma cells and that the chimeric, murine and reshaped anti-IL-6R antibodies were equivalent in their reactivities (text to Fig. 5 of the Sato reference). Furthermore, Sato also states that the reactivity of the reshaped antibody is equivalent to the original murine PM-1 antibody (pg 854). Applicants arguments that the chimeric PM-1 antibody has substantially the same activity as the reshaped antibody should also then conclude that the chimeric antibody has substantially the same activity as the original murine antibody. Therefore, no unexpected and superior results of the chimeric antibody are evident. It would have been an obvious choice for one of ordinary skill in the art at the time of the claimed invention to have made the chimeric antibody first (and more specially a murine-human chimeric) for use in human patients because one of ordinary skill in the art would have been motivated by the success in making chimeric and humanised antibodies as taught by Oi et al or Morrison.

5. No claims are allowed.

6. It is requested that a supplemental PTO-1449 be submitted with the complete citation including the author names and year of publication included. *No PTO-1449 of 3/13/00 was in file* 

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 28, 2000

*Geetha P. Bansal*  
GEETHA P. BANSAL  
PATENT EXAMINER